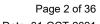




1.AER Number	(b) (6	3)	Ca	se Serio	usness: SE	RIOUS	Seriousr	iess Cri	teria: Do	eath					
						Patien	t Demograpi	nic							
Sex	Age		Height (	(cm)		Weight (k	g)	Race			Country V	/here Event	Occured		
FEMALE	14 YEARS							NO D	ATA - NO I	DATA	ROMANIA				
<u> </u>					E	vent Inforr	nation and N	larrative	)						
Verbatim Term	Lowes	st Level Term		Preferre	ed Term		Onset Dat	е	Event Seriousne	-	linical Out	c	rocedure ausality Per ompany	Proced Per Re	dure Causality porter
"it seems that" 2 days immunisation died	after Unkno	wn cause of dea	th	Death					SERIOUS	F.	ATAL	N	O DATA	NO DA	TΑ
This is a spontaneous	report from a c	ontactable physi	cian. This	report wa	as received via	a Pfizer sa	les represent	ative.							
A 14-year-old female primmunisation. The pat date. It was not report	ient medical his	story and concon	nitant med	/), via an lications v	unspecified ro were not report	ute of admi ed. The pa	nistration on tient experier	an unsp ced "it s	ecified date seems that"	e (Batch/Lo ' 2 days aft	t number w er immunis	as not report ation patient	ed) as single d died. The patic	lose for covent died on	vid-19 an unspecified
No follow-up attempts	ollow-up attempts are possible. The information about lot number and expiration date cannot be obtained. No further information is expected.														
<u> </u>						- 0.0	e Comments			<u>.</u>					
Based on the current a assessed. The case w The impact of this repo Any safety concern ide	ill be reassesse ort on the benef	ed if additional in fit/risk profile of t	formation he Pfizer i	becomes product is	available. evaluated as	part of Pfize	er procedures	for safe	etv evaluation	on. includin	a the revie	w and analvs	is of aggregate	e data for a	•
Lab Data:		Unknown				l	Lab Data								
Lab Narrative:															
Test Name		Normal Va	lue	Test Date	e	Test Resu	lt		Lab C	Comments					
1															
					Susp	ect Produc	t(s) Therapy	Informa	ation						
Suspect Product(s)		Unit Dose To	otal Daily	Dose	Regimen Dos	se Route	e of Admin	Therap	y Date(s)	Therapy [	Duration	Anatomical Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2						NO D	ATA	-				NO DATA			
					S	uspect Pro	oduct(s) Info	rmation		<u> </u>					
Suspect Product(s)		Indication(s)			Form of Adm	in Firs	t Total Daily	Dose	Action Ta	aken	Dechalle	nge	Rechallenge	Inte	eracting Drug
BNT162B2		COVID-19 imm	nunisation		SOLUTION F	OR			NOT APP	LICABLE	N/A		N/A	NO	DATA





1.AER Number		(b) (6)		Case Serie	ousness: SE	ERIOUS	Seriousne	ss Criteria:	Death					
					Pro	duct(s) and E	vent(s) Info	rmation						
Suspect Produ	ct(s)	Evei	nt(s)		CDS	Latency	Group	Rechallen	ge C	Causality pe	r Repo	rter	Causality	per Company
BNT162B2		Deat	th		N	Unknown		N/A	N	I/A			N/A	
						Patient Me	edical Histo	ry						
` Patient/Parent	Indicator	Coded Cond	dition	Start Date	Stop Date	Ongoing	g Note	s						
2				_		Cause of D	eath/Autop	sy						
Other Death Info														
Туре		Patient/Pare	ent Indicator	Coded Condit	ion				Notes					
DEATH		PATIENT		Death										
	nknown						tant Produc	t(s)						
Concomitant P	roduct(s)		Conmed '	radename As	Reported	Therapy Date	e(s)				Route	of Adm	n	
<u> </u>						-								
						Suspect or C	onmed Dev	rices						
Suspect Device						,								
Device Type	Device Indicator	Model No	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available fo Evaluation	Device r Evaluated Manufactu	by Irer Singl		Evaluati Type	on Evaluatio	n Code
NO DATA							NO DATA	NO DATA	NO DATA					
	'				'	Repo	rt History		,	,				
Source		HP/Medic	ally Case Re	port Type	Reporter	Occupation	Protocol/S	Study No.	Center ID & Ot	ther ID Pa	tient IC		itial Safety eceipt Date	EUDRACT No.
Spontaneous		Y	SPONT	ANEOUS	PHYSICIA	λN						2	3-JUL-2021	
		•	·			Refe	erences							
Reference Type	е		Reference ID			Reference No	tes			-				
LOCAL REFER	ENCE NO.		(b) (6)											
E2B COMPANY	NUMBER		(b	) (6)					·					
						Parent Me	edical Histor	ry						
Patient/Parent	Indicator	Coded Cond	dition	Start Date	Stop Date	Ongoing	g Note	s						





2.AER Number	(b)	(6)	Case Serio	usness: S	ERIOUS	Seriousne	ss Crite	ria: Death,Hos	spitalization Required,L	ife Threatening,Med	ically Significant
					Patient	Demographi	С				
Sex	Age		Height (cm)		Weight (kg)	)	Race		Country Where Eve	ent Occured	
MALE	12 YEARS						CAUCA	ASIAN - NO DATA	ITALY		
				E	Event Informa	ation and Na	rrative				
Verbatim Term	Lov	west Level Term	Preferre	ed Term		Onset Date		Event Seriousness	Clinical Outcome	Procedure Causality Per Company	Procedure Causality Per Reporter
septic shock	Sep	otic shock	Septic s	shock		08-JUL-202	ı s	SERIOUS	FATAL	NO DATA	NO DATA
This is a spontaneous A 12-year-old male par SINGLE for COVID-19 Ireflux, and respiratory vaccine included first c death). Date of death r Rocefin 2 g, Zithromax nsferase (normal rang 120- 240 IU/I): 1792 IL 140000- 440000 /mm3- 19627 IU/I and 10900 ng/ml all on 09Jul2021 253900 IU/I, lactate de with result 904 u/I and 021 with result 104.64 done.  Reporter's comment: It gastroesophageal refluctions for the sult information.  Follow-up (06Sep2021 death information.	tient receive immunisati infections. ( dose of COM reported as c 400 mg, Kr e: 5- 40 IU/I J/I, thrombop s): 59.00 x1( IU/I, lactate ; thrombopl shydrogenas range 5-40.  ng/ml and r t should be ux disease a	ed bnt162b2 (COMIRI on. Medical history in Concomitant medication of Miran and the constant of	NATY), dose 2 int cluded infantile cons included clob 21 for COVID-19 was in resuscitatic nitiated. The patie aminotransferase, C-reactive proteins and range: 0 - 0.5 for 10 ll	tramuscular, a erebral palsy of azam (FRSI) of immunisation on sedated with ent underwent (normal range in (normal range) 104.6 settine kinase: 3 ng/l, myoglobin ult 10900 ng/m 2021 with resurantile cerebral sician downloa	dministered in of the spastic of the spassic of the	n deltoid right tetraparesis trazole magnes 21, the patien and hemodial procedures v 341 IU/I, crea 5 15.68 mg/I, r 08Jul2021; alar 3.00 ng/ml, tr-270; Platelet and range 1-1 spastic tetrapares	on 03Ju ype, epil- sium (LU t experie ysis; adru which incu- tine kina myoglobi alanine a 47.38 mg ine amir rombopi crit on 0. 4; Findir	I20Ž1 20:31 (Lot I epsy (symptomati ICEN IESOMEPR enced septic shoc ministration of meluded Fibrin D direction of the see (normal range in blood (normal raminotransferase: 17: enia: 41.00x10 /m 8Jul2 eng: septic shock. The pe, epilepsy (symptomatical septic shock)	Number: ÉE2707; Éxpi c drug resistant), seve AZOLE MAGNESIUM] k which was considere rrem 760 mg, linezolid ner with unknown resu 224- 170 IU/I): 4664 IU ange: 20- 72 ng/ml): 30 3429 IU/I, aspartate arod: 30000 ng/ml, throm 27 IU/I, aspartate amin m3 all on 12Jul2021. A	ration Date: Oct2021 re intellectual disabili )); valproate sodium ( d serious (hospitaliza 1200 mg, fluconazol lts; alanine aminotra  //, lactate dehydroge 0000 ng/ml, thrombol minotransferase: 946 abopenia: 68.00 x10 / otransferase: 553 IU Aspartate aminotrans ent was fatal. It is unk c), severe intellectual	as DOSE 2, 0.3ML ty, gastroesophageal (DEPAKIN). Historical atton, life threatening, e, urbason 40 mg,  nase (normal range: penia (normal range: IU/I, creatine kinase: mm3, troponin: 105.08 /I, creatine kinase: ferase on 09Jul2021
	, ,				'						
Lab Data:		Present			La	ab Data					
Lab Narrative:											
Test Name		Normal Valu	ue Test Dat	te	Test Result	:		Lab Commer	its		
Alanine aminotransfera	ase	5 - 40	08-JUL-2	2021	*   904   10	J/I					
Alanine aminotransfera	ase	5 - 40	09-JUL-2	2021	*   3429	IU/I					
Alanine aminotransfera	ninotransferase 5 - 40 12-JUL-2021 *   1727		*   1727	IU/I							
Aspartate aminotransfo	erase	5 - 40	08-JUL-2	2021	*   341   IU	J/I					



2.AER Number	(b) (6)	Case Seriousness: S	ERIOUS	Seriousness Criteria:	Death, Hospitalization Required, Life Threatening, Medically Significant
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Test Name	Normal Value	Test Date	Test Result	Lab Comments
Aspartate aminotransferase	5 - 40	09-JUL-2021	*   904   IU/I	
Aspartate aminotransferase	5 - 40	09-JUL-2021	*   946   IU/I	
Aspartate aminotransferase	5 - 40	12-JUL-2021	*   553   IU/I	
Blood creatine phosphokinase	24 - 170	08-JUL-2021	*   4664   IU/I	
Blood creatine phosphokinase	24 - 170	09-JUL-2021	*   10900   IU/I	
Blood creatine phosphokinase	24 - 170	09-JUL-2021	*   19627   IU/I	
Blood creatine phosphokinase	24 - 170	11-JUL-2021	*   3791   IU/I	
Blood creatine phosphokinase	24 - 170	12-JUL-2021	*   253900   IU/I	
Blood creatine phosphokinase Blood lactate dehydrogenase Blood lactate dehydrogenase	120 - 240	08-JUL-2021	*   1792   IU/I	
Blood lactate dehydrogenase	120 - 240	09-JUL-2021	*   5856   IU/I	
Blood lactate dehydrogenase	120 - 240	12-JUL-2021	*   4184   IU/I	
Blood thromboplastin		08-JUL-2021	*   42.9   seconds	
Blood thromboplastin		09-JUL-2021	*   35.40   seconds	
Blood thromboplastin		11-JUL-2021	*   145   seconds	
C-reactive protein	0 - 5	08-JUL-2021	*   15.68   mg/l	
C-reactive protein	0 - 5	09-JUL-2021	*   47.38   mg/l	
C-reactive protein	0 - 5	12-JUL-2021	*   8.55   mg/l	
Fibrin D dimer	0 - 270	09-JUL-2021	*   10900   ng/ml	
Fibrin D dimer	0 - 270		*   unknown results   ng/ml	
Myoglobin blood	20 - 72	08-JUL-2021	*   30000   ng/ml	
Myoglobin blood	20 - 72	09-JUL-2021	*   30000   ng/ml	
Myoglobin blood	20 - 72	12-JUL-2021	*   15013.00   ng/ml	
Plateletcrit	0 - 0.5		*   104.64   ng/ml	
Thrombocytopenia Thrombocytopenia	140000 - 440000	08-JUL-2021	*   59.00 x10   /mm3	
Thrombocytopenia	140000 - 440000	09-JUL-2021	*   68.00 x10   /mm3	
Thrombocytopenia	140000 - 440000	12-JUL-2021	*   41.00x10   /mm3	
Troponin	0 - 0.5	08-JUL-2021	*   104.64   ng/ml	
Troponin	1 - 14	08-JUL-2021	*   3681   ng/L	
Troponin	0 - 0.5	09-JUL-2021	*   105.08   ng/ml	





2.AER Number	(b) (6)		Case Serio	usness: SEI	RIOUS <b>S</b> e	riousness C	Criteria: D	eath,Hospi	talization F	Required,Life <sup>-</sup>	Threatening	Medically	Significant
				Suspe	ct Product(s) Th	nerapy Infor	mation						
Suspect Product(s)	Unit	Dose Tot	al Daily Dose	Regimen Dos	e Route of A	dmin Thera	py Date(s)	Therapy I	Duration	Anatomical Location	Vaccinatio Dose No.	n Lot No	. Batch No.
BNT162B2	.3 n	nL .3 r	nL		INTRAMUS AR	CUL 03-JU 03-JU	IL-2021 - IL-2021			DELTOID RIGHT	2	FE270	7
				Sı	uspect Product(	s) Information	on						
Suspect Product(s)	Indi	cation(s)		Form of Admi	in First Tota	I Daily Dose	Action Ta	aken	Dechalle	enge	Rechalleng	je	Interacting Dru
BNT162B2	CO	VID-19 immu	nisation	SOLUTION FO	OR .3 mL		NOT APP	LICABLE	N/A		N/A		NO DATA
					duct(s) and Ever	nt(s) Informa	ation						
Suspect Product(s)	Event	(s)		CDS	Latency Gro	up	Rechallenge	•	Causalit	y per Reporte	er C	ausality p	er Company
BNT162B2	Septic	shock		N	Post Therapy		N/A		N/A		N	/A	
					Patient Medic	al History							
Patient/Parent Indicator	Coded Condit	ion	Start Date	Stop Date	Ongoing	Notes							
PATIENT	Cerebral palsy				NO DATA								
PATIENT	Epilepsy				NO DATA	symptom	natic drug res	istant					
PATIENT	Gastrooesopha disease	ageal reflux			NO DATA								
PATIENT PATIENT	Intellectual disa	ability			NO DATA	severe							
PATIENT	Respiratory tra	ct infection			NO DATA								
Other Death Information:					Cause of Deat	h/Autopsy							
Гуре	Patient/Paren	t Indicator	Coded Condition	on				Notes					
DEATH	PATIENT		Septic shock					110100					
ConMed: Present			'		Concomitant	t Product(s)							
Concomitant Product(s)		Conmed	Tradename As R	Reported	Therapy Date(s)					Route o	f Admin		
CLOBAZAM		FRISIUM			-					NO DAT	Ā		
ESOMEPRAZOLE MAGNE	ESIUM	LUCEN [E	SOMEPRAZOLE UM]	Ē	-					NO DAT	-A		
,		DEPAKIN								NO DAT			





2.AER Number		(b) (6)		Case Serie	ousness: SE	ERIOUS	Seriousne	ss Criteria	a: De	eath,Hospitalization	Required,Lif	e Threatenin	g,Medically	Significant
						Suspect or C	onmed Dev	rices						
Suspect Devic	es													
Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Availab Evaluat		Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluatio	n Code
NO DATA  Conmed Device							NO DATA	NO DAT	ГА	NO DATA				
Conmed Device	es		•		•	•		•						
Device Type				Model No.					Serial	No.				
NO DATA														
Ą						Repo	t History							
Source		HP/Medicall Confirmed	y Case Repo	ort Type	Reporter	Occupation	Protocol/	Study No.	Се	enter ID & Other ID	Patient II	D Initia Rece	I Safety eipt Date	EUDRACT No.
Spontaneous		Y	SPONTAN	EOUS	PHYSICIA	AN						26-JI	JL-2021	
			·		·	Refe	rences				·	·		
Reference Typ	е	Re	eference ID			Reference No	tes			-				
E2B AUTHORI	TY NUMBER		(b) (6)			(b) (6)								
E2B REPORT I	DUPLICATE		(b) (6)			(b) (6)								
<u> </u>						Parent Me	dical Histo	ry						
Patient/Parent	Indicator	Coded Condit	ion	Start Date	Stop Date	Ongoing	Note	s						
Patient/Parent														





3.AER Number		(b) (6)	)	С	ase Serio	usness: Si	ERIOU	S	Seriousn	ess C	riteria	: Death	1						
							Pa	atient [	Demograph	nic									
Sex	Age			Height	(cm)		Weig	ht (kg)		Rac	е			Country V	/here Event	Occured			
MALE	13 YEA	ARS								NO	DATA	- NO DAT	Α	MEXICO					
						F	vent l	nforma	ation and N	arrativ	/e								
Verbatim Term		Lowest	t Level Term		Preferr	ed Term			Onset Date		Eve	nt ousness	С	linical Out		rocedure ausality Pe ompany		roced er Rep	ure Causality oorter
13-year-old dies after receiving Pfizer vaccir	ne	Unknow	vn cause of d	eath	Death						SER	RIOUS	F.	ATAL	N	O DATA	N	O DAT	ΓA
This is a spontaneous COVID-19 mRNA VAC history was not reporte autopsy was performe No follow-up attempts	CCINE), ed. Cond ed and th	unknow comitant ne cause	n dose numb medications of death was	er, via an u were not re not provid	nspecified ported. It ed.	l route of admi was reported t	nistration hat the	on on a	ın unspecifi	ed date	e (Bato	h/Lot Nur	nber: u	nknown) a	s a single do	se for COVI	D-Ì9 imr	nunisa	tion. Medical
Lab Data:			Unknow	n				La	b Data										
Lab Narrative:																			
Test Name			Normal	<b>Value</b>	Test Dat	e	Test F	Result				Lab Com	ments	i					
<u> </u>																			
						Susp	ect Pro	oduct(s	s) Therapy	Inforn	nation								
Suspect Product(s)			Unit Dose	Total Daily	/ Dose	Regimen Do	se   F	Route	of Admin	Thera	py Dat	e(s) The	erapy I	Duration	Anatomical Location	Vaccination Dose No.	on Lot N	No.	Batch No.
BNT162B2							1	NO DA	TA	-					NO DATA				
\$						5	Suspec	t Prod	uct(s) Info	rmatio	n								
Suspect Product(s)			Indication(s	)		Form of Adn	nin	First	Total Daily	Dose	Acti	ion Taken	1	Dechalle	nge	Rechallen	ge	Inte	acting Drug
BNT162B2			COVID-19 ir	nmunisatio	า	SOLUTION F INJECTION	OR				NO	Γ APPLICA	ABLE	N/A		N/A		NO I	DATA
						Pro	duct(s	s) and l	Event(s) In	forma	tion								
Suspect Product(s)		E	vent(s)			CDS	La	atency	Group	F	Recha	llenge		Causality	per Report	er (	Causality	per (	Company
BNT162B2		De	eath			N	Ur	nknown	1	١	N/A			N/A		١	I/A		
							Pat	tient M	edical Hist	ory									
Patient/Parent Indica	tor C	oded Co	ondition	Sta	rt Date	Stop Date		Ongoin											
Other Death I for the							Cau	use of I	Death/Auto	psy									
Other Death Information	on:														F	DA-CBER-2	2022-581	2-023	5502





3.AER Number		(b) (6)		Case Serie	ousness: SE	ERIOUS	Seriousnes	ss Criteria:	Death					
Туре		Patient/Parent	Indicator Co	oded Condit	ion				Notes					
DEATH		PATIENT	De	eath										
ConMed: Ur	ıknown					Concomi	tant Produc	t(s)						
Concomitant P	roduct(s)		Conmed Tra	dename As	Reported	Therapy Dat	e(s)				Route	of Admin		
						-								
Suspect Device						Suspect or C	Conmed Dev	ices						
Suspect Device														
Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Singl	e Use   E	Evaluation Type	Evaluatio	n Code
NO DATA							NO DATA	NO DATA	NO DATA					
II.						Repo	rt History							
Source		HP/Medically Confirmed	/ Case Repo	rt Type	Reporter	Occupation	Protocol/S	Study No.	Center ID & Other	ID Pa	itient ID		I Safety ipt Date	EUDRACT No.
Spontaneous		N	SPONTANE	EOUS	NA							26-JI	JL-2021	
)						Refe	erences							
Reference Typ	e	Re	ference ID		I	Reference No	tes							
NCSP		(b)	(6)											
E2B COMPANY	NUMBER		(b) (l	6)										
						Parent Me	edical Histor	у						
Patient/Parent	Indicator	Coded Conditi	on	Start Date	Stop Date	Ongoin	g Note	S						
Patient/Parent														
) 														
מ														





Section Page: 1

4.AER Number Case Seriousness: **SERIOUS** Seriousness Criteria: Death, Hospitalization Required, Life Threatening, Medically Significant (b) (6)

			Patient Demographi	С	
Sex	Age	Height (cm)	Weight (kg)	Race	Country Where Event Occured
FEMALE	15 YEARS	188.0	56.0	NO DATA - NO DATA	FRANCE

		Even	t Information and Narrat	tive			
Verbatim Term  Cardiac arrest/asystole	Lowest Level Term	Preferred Term	Onset Date	Event Seriousness	Clinical Outcome	Procedure Causality Per Company	Procedure Causality Per Reporter
Cardiac arrest/asystole	Cardiac arrest	Cardiac arrest	13-JUL-2021	SERIOUS	FATAL	NO DATA	NO DATA
Anoxia cerebral	Anoxia cerebral	Brain hypoxia		SERIOUS	FATAL	NO DATA	NO DATA
vegetative coma	Coma	Coma	30-JUL-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
retro-rolandic aspect of brain death	Brain death	Brain death	30-JUL-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
asthenia	Asthenia	Asthenia	11-JUL-2021	NONSERIOUS	UNKNOWN	NO DATA	NO DATA
arm pain	Pain in arm	Pain in extremity	11-JUL-2021	NONSERIOUS	UNKNOWN	NO DATA	NO DATA
headaches D	Headache	Headache	12-JUL-2021	NONSERIOUS	UNKNOWN	NO DATA	NO DATA

ontaneous report from a contactable physician downloaded from the European Medicines Agency (EMA) EudraVigilance

A 15-year-old female patient received bnt162b2 (COMIRNATY), intramuscular on 11Jul2021 07:30 (Lot Number: Unknown) (at the age of 15-year-old) as dose 1, single for COVID-19 immunization. Medical history included ongoing asthma, ongoing Barlow's syndrome, ongoing Marfan's syndrome. The patient's concomitant medications were not reported. In good health overall, apart from a loss of 10kg over gone year (since entering high school). During the day (11Jul2021), asthenia and isolated arm pain. The next day (12Jul2021), headaches yielding under Doliprane. On 13Jul2021, around 16:30 (last moment conscious view), her mother drops her off to her father. Father watered the garden and she cleaned the garage to prepare for her birthday party. On 13Jul2021 17:20, her father found her in cardio respiratory arrest, back to the ground, next to a ladder. No flow was unknown. At 17:30 arrival of firefighters: 2 external electric shocks were given and 1 mg of adrenaline injected. Moderately reactive opupils. At 17:50 arrival of Specialist mobile emergency unit: asystole (Life-threatening). Two injections of 1 mg of adrenaline, transition to ventricular fibrillation.

external electric shock, 2 ampule of Cordarone and one ampule of Calcium Gluconate. Return to regular sinus rythme without disturbance of repolarization and resumption of a pulse. Orotracheal intubation (probe no 6). New: 1 external electric shock, one ampule of Cordarone and 1 mg of adrenaline. Return of a sinus rhythm but presence of a sub ST in infero lateral. 90/60 mmHg arterial pressure excluding Sedation. Tight areactive bilateral miosis pupils. Ventilated in Ventilator-Associated Conditions but presence of spontaneous ventilation requiring sedation by Hypnovel and Sufentanyl and 10 mg of Nimbex. Apraallel introduction of Noradrenaline 0.8 mg/h. No filling. In total: low flow of 30 minutes. Recovered and transfer to intensive care. Examinations: biology: complete blood count normal, C-reactive protein 1.4. Coroner considered as normal no coronary dissection. Computed tomography scan Computed tomography arterial portography: No aortic dissection or large vsx, no intracranial bleeding, the super sigmoid aortography does not show any aortic insufficiency. The ascending aorta is moderately dilated. Computerised tomogram head: no bleeding, no traumatic injury. Electrocardiogram: Not very evocative. Respiratory rate. Maintenance of sedation, temperature control at 36 degrees. Complicated cardiac arrest of

a Takotsubo. Trans-thoracic echocardiography finding a 30% altered left ventricular ejection fraction with kinetic disorders suggestive of Takotsubo (post stress?). More doubt about intra-left ventricular thrombus. Low left ventricular filling pressures. Integral time speed= 8. Inferior vena cava= 15. 15Jul2021 Appearance in the morning of continual clonies of the multiple sulfatase deficiency, put under Keppra increased to 750x2. Electroencephalography results pending + Left transcranial doppler more disturbed than the right (Vdiastolic 20 vs 40 on the right), Control contrast enhanced computed tomography scan superimposable at the level of large vsx, but appearance of parenchymal parenchymal hemispherical hemispherical right upper cerebellar areas of ischemic appearance. 20Jul2021 pathological awakening, inhalation lung disease, myocarditis assessment in progress (negative). 23Jul2021 no sign of wakign up flat electroencephalogram alternating with a few waves of intermittent activity. Computered tomography scan stability of ischemic lesions appearance of cerebral edema compatible with anoxo-ischemic lesions, put under Mannitol. Cardio: cardiac magnetic resonance imaging in favor of a takotsubo, myocarditis unl kely, infective and immunological workup negative. 27Jul2021 Pathological electroencephalogram





Section Page: 2

4.AER Number

(b) (6)

Case Seriousness:

SERIOUS

Seriousness Criteria:

Death, Hospitalization Required, Life Threatening, Medically Significant

, Keppra introduction. Computered tomography scan increase in cerebral edema reaching almost the entire sustentorial stage, sudden episodes of desaturation. The COVID serology returns positive (Ig G antiS and antiN and IgM), re-reading of the entry serology concluded with a Covid infection starting at the same time as the anti-covid vaccination. 30Jul2021 retro-rolandic aspect of brain death, vegetative coma. Decision to limit therapy. Complete file no further information. The patient died on 07Aug2021. An autopsy was not performed. Cause of Death: Anoxia cerebral and Cardiac arrest while outcome of the other events was unknown.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Lab Data:	Present		Lab Data	
Lab Narrative:				
Test Name	Normal Value	Test Date	Test Result	Lab Comments
7				
Blood pressure increased		13-JUL-2021	*   90/60   mmHg	
Body temperature decreased		13-JUL-2021	*   36   Centigrade	
Computerised tomogram		13-JUL-2021	*   The ascending aorta is moderately dilated	No aortic dissection or large vsx, no intracranial bleeding, the super sigmoid aortography does not show any aortic insufficiency
Computerised tomogram		15-JUL-2021	*   appearance of parenchymal parenchymal hemispherica	appearance of parenchymal parenchymal hemispherical hemispherical right upper cerebellar areas of ischemic appearance
Computerised tomogram head		13-JUL-2021	*   no bleeding	no traumatic injury
Computerised tomogram head		23-JUL-2021	*   stability of ischemic	lesions appearance of cerebral edema compatible with anoxo-ischemic lesions, put under Mannitol
Computerised tomogram head		27-JUL-2021	*   increase in cerebral edema	reaching almost the entire sustentorial stage, sudden episodes of desaturation.
C-reactive protein		13-JUL-2021	*   1.4	
Echocardiogram			*   finding a 30%	altered left ventricular ejection fraction with kinetic disorders suggestive of Takotsubo
Electrocardiogram		13-JUL-2021	*   Not very evocative	Respiratory rate
Electroencephalogram		23-JUL-2021	*   flat	with a few waves of intermittent activity
Electroencephalogram		27-JUL-2021	*   Pathological	Keppra introduction
Full blood count		13-JUL-2021	*   normal	
Magnetic resonance imaging		13-JUL-2021	*   cardio	in favor of a takotsubo
SARS-CoV-2 ant body test positive		13-JUL-2021	POSITIVE   positive	(Ig G antiS and antiN and IgM), re-reading of the entry serology concluded with a Covid infection starting at the same time as the anti-covid vaccination
Ultrasound Doppler		13-JUL-2021	*   left more disturbed	than the right (Vdiastolic 20 vs 40 on the right)

Suspect Product(s) Therapy Information										
Suspect Product(s)	Unit Dose	Total Daily Dose	Regimen Dose	Route of Admin	Therapy Date(s)	Therapy Duration		Vaccination Dose No.	Lot No.	Batch No.
BNT162B2				INTRAMUSCUL AR	11-JUL-2021 - 11-JUL-2021		NO DATA	1	Unknown	

FDA-CBER-2022-5812-0235505





4.AER Num	ber	(b) (6)		Case Serio	usness: SE	RIOU	S <b>Seric</b>	usness C	Criteria: Death,Hosp	italization Requ	iired,Life Threaten	ing,Medica	lly Significant
					s	uspec	t Product(s)	Informati	on				
Suspect Pro	oduct(s)	In	dication(s)		Form of Adm	in	First Total D	aily Dose	Action Taken	Dechallenge	Rechalle	enge	Interacting Drug
BNT162B2		С	OVID-19 immu	nisation	SOLUTION F	OR			NOT APPLICABLE	N/A	N/A		NO DATA
						•	s) and Event(s	•					
Suspect Pro	oduct(s)	Eve	nt(s)		CDS		tency Group		Rechallenge	Causality pe	r Reporter	Causalit	y per Company
BNT162B2		Card	liac arrest		N	Po	ost Therapy		N/A	N/A		N/A	
BNT162B2		Braiı	n hypoxia		N	Ur	nknown		N/A	N/A		N/A	
BNT162B2		Com	а		N	Po	ost Therapy		N/A	N/A		N/A	
BNT162B2		Braiı	n death		N	Po	ost Therapy		N/A	N/A		N/A	
BNT162B2		Asth	enia		Y	Pr	e-Therapy		N/A	N/A		N/A	
BNT162B2		Pain	in extremity		Y	Pr	1,		N/A	N/A		N/A	
BNT162B2		Head	dache		Υ	Po	ost Therapy		N/A	N/A		N/A	
5						Pat	tient Medical	History					
Patient/Par	ent Indicator	Coded Cond	lition	Start Date	Stop Date	Ic	Ongoing	Notes					
PATIENT		Asthma					ONGOING						
T PATIENT		Marfan's syn	drome				ONGOING						
PATIENT		Mitral valve	rolapse				ONGOING						
Other Death	Information:					Cau	ise of Death/	Autopsy					
 ∩Type		Patient/Pare	nt Indicator	Coded Condition	n				Notes				
DEATH		PATIENT		Brain hypoxia									
DEATH		PATIENT		Cardiac arrest									
ConMed:	Unknown					Co	oncomitant P	roduct(s)					
Concomita	nt Product(s)		Conmed 1	radename As R	eported	Thera	py Date(s)				Route of Admin		
						-							
									<u> </u>				





4.	AER Number		(b) (6)		Case Serie	ousness: SE	ERIOUS	Seriousnes	ss Criteria:	Dea	ath,Hospitalizatior	Required,Lit	fe Threatenin	g,Medically	Significant
							Suspect or C	onmed Dev	ices						
Sı	uspect Device	es					<u> </u>								
D	evice Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available fo Evaluation	r	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation	n Code
GMT	O DATA							NO DATA	NO DATA		NO DATA				
Ġ							Repoi	t History							
ς: Si	ource		HP/Medicall Confirmed	y Case Repo	rt Type	Reporter	Occupation	Protocol/S	Study No.	Cer	nter ID & Other ID	Patient II	D Initia Rece	I Safety eipt Date	EUDRACT No.
42st	pontaneous		Y	SPONTANE	EOUS	PHYSICIA	λN						16-A	UG-2021	
9							Refe	rences							
R	eference Typ	e	Re	eference ID			Reference No	tes			-				
щE	2B AUTHORIT	Y NUMBER	2	(b) (6)			(b) (6)								
<b>1</b> 9€2	2B REPORT D	UPLICATE		(b) (6)			(b) (6)								
<u>.</u>								dical Histor	<u> </u>						
₫Pi	atient/Parent	Indicator	Coded Conditi	ion	Start Date	Stop Date	Ongoing	Note	s						
اهر															
這															
آھ															
ij															
6															
8															
75															
66															
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17															
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Ö															





Section Page: 1

5.AER Number (b) (6) Case Seriousness: SERIOUS Seriousness Criteria: Death, Hospitalization Required, Life Threatening, Medically Significant

	Patient Demographic										
Sex	ex Age Height (cm) Weight (kg) Race Country Where Event Occured										
MALE	13 YEARS	140.0	32.0	NO DATA - NO DATA	GERMANY						

		Event Inform	ation and Narrat	ive			
Verbatim Term  Disseminated intravascular	Lowest Level Term	Preferred Term	Onset Date	Event Seriousness	Clinical Outcome	Procedure Causality Per Company	Procedure Causality Per Reporter
Disseminated intravascular coagulation	Disseminated intravascular coagulation	Disseminated intravascular coagulation	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Lung hemorrhage	Lung hemorrhage	Pulmonary haemorrhage	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Pyrexia	Pyrexia	Pyrexia	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Multiorgan failure	Multiorgan failure	Multiple organ dysfunction syndrome	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
Septic shock	Septic shock	Septic shock	13-AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
haemorrhagic hemithorax	Thoracic haemorrhage	Thoracic haemorrhage	AUG-2021	SERIOUS	FATAL	NO DATA	NO DATA
massive liver failure	Liver failure	Hepatic failure	AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
creatinine elevated	Blood creatinine increased	Blood creatinine increased	AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
bleeding in bladder and abdomen	Intra-abdominal bleeding	Intra-abdominal haemorrhage	AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
bleeding in bladder and abdomen	Urinary bladder bleeding	Urinary bladder haemorrhage	AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
anuria	Anuria	Anuria	AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
respiratory insufficient	Respiratory failure	Respiratory failure	13-AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
epilepticus	Status epilepticus	Status epilepticus		SERIOUS	UNKNOWN	NO DATA	NO DATA
At admission the platelets were 150.000/ml and declined to 53.000/ml	Platelets decreased	Platelet count decreased	13-AUG-2021	SERIOUS	UNKNOWN	NO DATA	NO DATA
Inappropriate schedule of vaccine administered	Inappropriate schedule of vaccine administered	Inappropriate schedule of product administration	11-AUG-2021	NONSERIOUS	UNKNOWN	NO DATA	NO DATA



Seriousness Criteria: Death, Hospitalization Required, Life Threatening, Medically Significant



5.AER Number

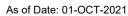
(b) (6)

Section Page: 2

This is a superference was self-free a second		ND da	lad forms that From a se	- Madiainaa Amanay (EMA) E		/b\ /c\	A 40 was ald made mations as as is all
This is a spontaneous report from a non-second dose of bnt162b2 (COMIRNATY, immunization. The patient's medical histo respiratory insufficiency, reflux oesophagi broncho pulmonal dysplasia including imperformed without major deteriation (last addition, the patient received a major hip	Solution for Injection ry included extreme tits on an unspecified blementing a liquor scontrol 2 weeks prior to the solution of the solution o	n, Lot Numb ly preterm (le d date. The լ shunt. Furthe r to death). <i>I</i>	er: 10020A) via an ur ess than 28 weeks), loatient born at gestater complication was a At the age of ten year	nknown route of administration Hypox-ic-ischaemic encephal ion 24+4 with Grad iV (right) it treatment resistant epilepsy the patient received a repair	n on 11Aug2021 opathy, posthaen and Grad II (left) i despite long term of the gastroesop	norrhagic hydrocephalus ntra cranial heamorrage treatment with Valproate	, symptomatic epilepsy, dysphagia, Further complication post-natal were B. Regular control of liver function ware
received first dose of bnt162b2 (COMIRN reported. The patient underwent lab tests patient experienced multiorgan failure, lur reported as death, hospitalization and life 150.000/ml and declined to 53.000/ml afted death of the patient. Status epilepticus on failure, anuria, creatinine elevated, bleedi	and procedures wh ng hemorrhage, diss threatening. At adm er app. 12h treatmen admission. So far a	ich included eminated inf nission on the nt. In addition bout 1-2 sei	platelets min 3410x 3 ravascular coagulation of 13Aug2021 the paton, the coagulation systems of the coagulation systems per month, seiz	31uml, Quick <10, INR>4.9, p on, pyrexia and septic shock o ient was respiratory insufficie stem deteriorated and finally t zures also always during feve	TT >180 sec, proof on 13Aug2021. The second and needed into the patient appear. Therapy with IV.	BNP 24937 pg/ml, Trop he patient died on 14Aug ubation and ventilation. A red with a haemorrhagic /IG and cortisone. In the	T 1580 pg/ml on an unknown date. The g2021. Seriousness for the events was At admission the platelets were hemithorax which eventually lead to
ls will follow. Outcome of multiorgan failur Relatedness of drug to reaction(s)/event (	re, lung hemorrhage (s) Source of assess	, disseminat ment PEI. R	ed intravascular coag esult of Assessment	julation, pyrexia and septic sh D. Unclassifiable.	nock, Thoracic ha	emorrhage was fatal, ou	tcome of other events was unknown.
Sender Comment: Platelets min 3410^31 blande, no signs of meningitis. Blood cult cortisone.							
No follow-up attempts poss ble. No furthe	r information expect	ed.					
Follow-up (23Aug2021 and 24Aug2021): Included: new events (liver failure, anuria Status epilepticus), lab tests, medical hist	, creatinine elevated	, bleeding in	bladder and abdome	en, haemorrhagic hemithorax,			
Follow-up (30Aug2021): New information	r						
<u> </u>							
eceived from product quality complaints o	lepartment included	no investiga	ation could be perforr	ned due to batch/lot no. provi	ded within source	e doc was not found to be	e valid.
No follow-up attempts poss ble. No furthe	r information expect	ed.					
Lab Data:	Present			Lab Data			
Lab Narrative:							
Test Name	Normal Value	Test Date	Test R	esult	Lab Comments	5	
Activated partial thromboplastin time			*   >1	80   seconds			
Amniotic fluid index			*   sh of mer	unt in place blande, no signs ingitis			
Blood culture			*   No	t yet avalaiable			
International normalised ratio			*   4.9	)			
Liver function test			*   wit	h out major deteriation			
N-terminal prohormone brain natriuretic peptide			*   24	937   pg/mL		_	
						F	DA-CRER-2022-5812-0235509

Case Seriousness: SERIOUS







5.AER Number	(b) (6)	Case Seriousness: SERI	OUS Seriousness Criteria:	Death.Hospitalization Required.Life Threatening.Medically Significant
J.ALIN Hullibel	(0) (0)	ouse delibusiless. OLIVI	Joo deriousiless differia.	Death, 103phanzation required, Life Threatening, we do any digitile and

Test Name	Normal Value	Test Date	Test Result	Lab Comments
Platelet count		13-AUG-2021	*   150.000	/ml
Platelet count		13-AUG-2021	*   53.000	/m
Platelet count			*   3410^31	min 3410x31uml
Prothrombin time			*   <10	
Troponin T			*   1580   pg/mL	

<u> </u>											
Suspect Product(s) Therapy Information											
Suspect Product(s)	Unit Dose	Total Daily Dose	Regimen Dose	Route of Admin	Therapy Date(s	S) Therapy [	Duration	Anatomical Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2	.3 mL	.3 mL		NO DATA	11-AUG-2021 - 11-AUG-2021			NO DATA	2	10020A	
d d	·		Susp	ect Product(s) Info	ormation						
Suspect Product(s)	Indication(	s)	Form of Admin	First Total Dail	y Dose Action	Taken	Dechalle	enge	Rechallenge	In	teracting Drug
BNT162B2	COVID-19 i	mmunisation	SOLUTION FOR INJECTION	.3 mL	NOT A	PPLICABLE	N/A		N/A NO		O DATA





Section Page: 4

5.AER Number	(b) (6)	Case Seriousness: SERIOUS	Seriousness Criteria:	Death, Hospitalization Required, Life Threatening, Medically Significant
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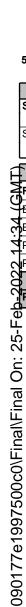
						Product(s) and Event(s) Information  CDS   Letency Crown   Rephallenge   Councility per Reporter   Councility per Company										
Suspect Product(s)	Event(s)	CDS	Latency Group	Rechallenge	Causality per Reporter	Causality per Company										
BNT162B2	Disseminated intravascular coagulation	N	Post Therapy	N/A	N/A	N/A										
BNT162B2	Pulmonary haemorrhage	N	Post Therapy	N/A	N/A	N/A										
BNT162B2	Pyrexia	N	Post Therapy	N/A	N/A	N/A										
BNT162B2	Multiple organ dysfunction syndrome	N	Post Therapy	N/A	N/A	N/A										
BNT162B2	Septic shock	N	Post Therapy	N/A	N/A	N/A										
BNT162B2	Thoracic haemorrhage	N	Unknown	N/A	N/A	N/A										
BNT162B2	Hepatic failure	N	Unknown	N/A	N/A	N/A										
BNT162B2	Blood creatinine increased	N	Unknown	N/A	N/A	N/A										
BNT162B2	Intra-abdominal haemorrhage	N	Unknown	N/A	N/A	N/A										
BNT162B2	Urinary bladder haemorrhage	N	Unknown	N/A	N/A	N/A										
BNT162B2	Anuria	N	Unknown	N/A	N/A	N/A										
BNT162B2	Respiratory failure	N	Post Therapy	N/A	N/A	N/A										
BNT162B2	Status epilepticus	N	Unknown	N/A	N/A	N/A										
BNT162B2	Platelet count decreased	N	Post Therapy	N/A	N/A	N/A										
BNT162B2	Inappropriate schedule of product administration	Y	<= 1 day	N/A	N/A	N/A										
		•	Patient Medical Histo	ory												





5.AER Number	(b) (6)		Case Serio	ousness: SE	ERIOUS	Seriousnes	ss Criteria: De	eath,Hospitalizatio	n Required,L	ife Threatenin	g,Medically Significant
Patient/Parent Indicator	Coded Condition	on	Start Date	Stop Date	Ongoing	g Note	S				
PATIENT	Bronchopulmon	ary dysplasia			NO DAT	·A					
PATIENT	Dysphagia										
PATIENT	Epilepsy										
PATIENT	Gastrooesophaç disease	geal reflux									
PATIENT	Haemorrhage in	ntracranial			NO DAT	A born	at gestation 24+4	4 with Grad iV (righ	nt) and Grad	II (left) intra cr	anial heamorrage
PATIENT	Hip deformity				NO DAT	A					
PATIENT	Hip surgery				NO DAT	A					
PATIENT	Hypoxic-ischaer encephalopathy	mic '									
PATIENT	Posthaemorrhag hydrocephalus	gic									
PATIENT	Premature baby	1									
PATIENT	Respiratory failu	ıre									
					Cause of D	Death/Autop	sy				
Other Death Information:											
Туре	Patient/Parent		oded Conditi					Notes			
DEATH	PATIENT			ntravascular co							
DEATH	PATIENT			dysfunction syn	drome						
DEATH	PATIENT		ulmonary hae	morrhage							
DEATH	PATIENT	P	yrexia								
DEATH	PATIENT	S	eptic shock								
DEATH	PATIENT	Т	horacic haem	orrhage							
ConMed: Unknown		1			Concomi	tant Produc	t(s)				
Concomitant Product(s)		Conmed Tra	adename As I	Reported	Therapy Dat	e(s)			Rout	e of Admin	
					-						
					Suspect or C	Conmed Dev	ices				
Suspect Devices											
Device Type Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA						NO DATA	NO DATA	NO DATA			
	<u> </u>		-	1			1	1	1	1	







5.AER Number	(b) (6)	Case Seriousness:	SERIOUS	Seriousness Criteria:	Death, Hospitalization Required, Life	Threatening, Medically Significant
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			Report	t History			
Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	Y		OTHER HEALTH PROFESSIONAL			19-AUG-2021	

-1										
$\mathbf{H}$							Reference	s		
Z	Reference Type	R	eference ID			Referen	nce Notes			
Ч	E2B AUTHORITY NUMBER	D	E-PEI-2021001	168078		PEI				+
34	E2B REPORT DUPLICATE	D	E-PEI-2021001	168078		PEI				+
4	PRODUCT COMPLAINT NO	D. 62	84782			CITI PR	: ID			+
Š	PRODUCT COMPLAINT NO	D. IN	T-183670			INT ID				
g						Par	ent Medical I	History		
7	Patient/Parent Indicator	Coded Condi	ion	Start Date	Stop Date	<b>●</b> 0	ngoing	Notes		





6.AER Number	(b) (6)		Ca	ise Serio	usness: SE	ERIOU	S <b>Serious</b>	ness	Criteria	a: Dea	th						
						P	atient Demogra	ohic									
Sex A	ge		Height	(cm)		Weig	ht (kg)	Ra	ice			Country V	/here Event	Occured			
MALE 1	5 YEARS							NC	DATA	- NO DA	TA .	AUSTRIA					
					Е	vent I	nformation and	Narra	tive								
Verbatim Term  Death/NOS death	Lowest Le	evel Term		Preferre	ed Term		Onset Da	ite	Eve Ser	ent iousnes		linical Out	0	Procedure Sausality P Company		Proced Per Rep	ure Causality porter
•	Unknown o			Death			20-JUL-2			RIOUS		ATAL	İ	IO DATA		NO DAT	ΓΑ
15-year-old male patient concomitant medications Also reported on 20Jul20 Sender Comment: BASC	his is a spontaneous report from a contactable physician downloaded from the European Medicines Agency (EMA) EudraVigilance-WEB Regulatory Authority number  (b) (6) . A 5-year-old male patient received bnt162b2 (COMIRNATY), dose 1 intramuscular on 01Jul2021 (Batch/Lot Number: FD6840) as dose 1, single for covid-19 immunisation. The patient medical nistory and concomitant medications were none. Patient was found dead in bed on the morning of 20Jul2021. There were no known previous illnesses. The forensic autopsy could not find a cause of death until today. so reported on 20Jul2021 the patient experienced death/NOS death. An autopsy was performed, and results were not provided.  The patient experienced death/NOS death and results were not provided.  The patient experienced death/NOS death and results were not provided.  The patient experienced death/NOS death and results were not provided.  The patient experienced death until today. The patient experienced de																
Lab Data:		Unknowi	า				Lab Data										
Lab Narrative:																	
Test Name		Normal \	/alue	Test Dat	е	Test I	Result			Lab Co	mments	•					
I					Susp	ect Pr	oduct(s) Therap	y Info	rmatio	า							
Suspect Product(s)	Un	it Dose	Total Daily	Dose	Regimen Do	se I	Route of Admin	Ther	apy Da	te(s) T	nerapy [	Ouration	Anatomical Location	Vaccinat Dose No.		No.	Batch No.
BNT162B2							INTRAMUSCUL AR		JL-202 JL-202		DAY(S)		NO DATA	1	FD	6840	FD6840
BNT162B2	<u> </u>					Suspe	ct Product(s) Inf	ormat	ion								
Suspect Product(s)	Inc	dication(s	)		Form of Adn	nin	First Total Dai	y Dos	e Ac	tion Take	n	Dechalle	nge	Rechaller	nge	Inte	racting Drug
BNT162B2	CC	OVID-19 im	nmunisation	1	SOLUTION F INJECTION	OR			NO	T APPLI	CABLE	N/A		N/A		NO I	DATA
Support Braduct/a					Pro	duct(s	s) and Event(s)	nform	ation								
Suspect Product(s)	Even	ıt(s)			CDS	La	atency Group		Recha	allenge		Causality	per Report	er	Causali	ity per (	Company
BNT162B2	Deatl	h			N	Po	ost Therapy		N/A			N/A			N/A		
						Pa	tient Medical Hi	story									
Patient/Parent Indicato	r   Coded Cond	lition	Star	rt Date	Stop Date		Ongoing N	otes									





6.AER Number	r	(b) (6)		Case Serie	ousness: SE	RIOUS	Seriousnes	s Criteria: L	Jeath					
						Cause of D	Death/Autops	sy						
Other Death Inf	formation:	Patient/Pare	nt Indicator	Coded Condit	ion				Notes					
Type DEATH		PATIENT	iit iiiuicatoi	Death	1011				Notes					
	one	77112141		Dodaii		Concomi	itant Product	:(s)						
Concomitant F			Conmed T	radename As	Reported	Therapy Dat		(-)			Route	of Admin		
₹ <u> </u>						-								
4						Suspect or C	Conmed Dev	ces						
Suspect Devic	es					•								
Device Type	Device Indicator	Model No	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single	Use	Evaluation Type	Evaluatio	n Code
ONO DATA							NO DATA	NO DATA	NO DATA					
Щ						Repo	rt History							
Source		HP/Medica Confirmed	ally Case Re	port Type	Reporter	Occupation	Protocol/S	tudy No.	Center ID & Other II	D Pat	ient IC		l Safety ipt Date	EUDRACT No.
Spontaneous		Y	SPONTA	NEOUS	PHYSICIA	AN						23-A	JG-2021	
: <del></del>						Refe	erences							
Reference Typ	e	I	Reference ID		I	Reference No	tes							
E2B AUTHORI	TY NUMBER	₹	(b)	(6)		(b) (6)								
E2B REPORT I			(b)	(6)		(b) (6)								
PRODUCT CO			(b) (6)			(b) (6)								
PRODUCT CO	MPLAINT N	0.	(b) (6)		(	b) (6)	dical Higtor	.,						
Patient/Parent	Indicator	Coded Cond	ition	Start Date	Stop Date	Ongoing	edical Histor							
T. ationior arent	maicator	Coded Conc	111011	Start Date	Otop Date	Chigoni	y Hotes							





7.AER Number		(b) (6)	Ca	ase Serio	usness: SE	ERIOUS	Seriousn	ess Criter	<b>ia</b> : De	eath,Medically Sign	ificant			
						Patient I	Demograph	ic						
Sex	Age		Height	(cm)		Weight (kg)	ı	Race		Country	Where Event	Occured		
MALE	15 YE/	ARS						ASIAN -	NO DAT	A JORDAN	I			
					E	vent Informa	ation and N	arrative						
Verbatim Term respiratory and circu		Lowest Level Term		Preferr	ed Term		Onset Date		ent eriousne	Clinical C		Procedure Causality Per Company		dure Causalit eporter
respiratory and circu failure	ılatory	Respiratory failure		Respira	tory failure		13-AUG-20	21 SE	ERIOUS	FATAL		NO DATA	NO DA	ATA
respiratory and circu failure	•	Circulatory failure			ory collapse		13-AUG-20		RIOUS	FATAL		NO DATA	NO DA	
vaccination, was not death on the report COVID-19. The patidose on 31Aug21. Covide and the covid	diagnose was respin on 09Sep2 dose vial xevent for les were ide batch and ved batch 121): New in for death	from a contactable con- ation, administered in the dical history and con- ded with COVID-19. On ratory and circulatory factor treatment received. The 2021, the investigations of the factor of the factor of the act of the factor of the facto	13Aug202' ailure (13Ai he outcom al results for date: FF2 sonably su stigation. T eptable. Til h met the o om the pat piratory and	1 at 04:30 ug2021 at lee of the eor the product of the eor the product of the pro	, the patient pate to 4:30). The e to 4:30). The e swents was fata duct description 2021 with descrice malfunction impact on procrocess determed requirement der included: depry failure adde	assed away w vent resulted il. The reporte n: compound ription of com n: no; severity duct quality, i ined that no r s at time of re eath certificate ed.	ithout any hin emergend rinformed the both 162 coving laint: produce of harm was regulatory, vegulatory no lease. Final e and the initial control of the both the	istory of illication was a different it was a different was a different in the confirmation was a diffication was a diff	ness. On epartmen not repor not suspe investiga icable, s nd stabil vas requi on status	otsSep2021, the retor urgent care. The ted if an autopsy wension for intramulation request: requeite sample status wity. The PGS Puursred. No corrective is: not confirmed; rosy (final report not	eporter informene patient since a partient since as performed.  Dest for investiguas not receive a conclude that or preventive a cot cause: non-	ed that it was ree the vaccination. The patient was ations for vacced. The summand the reported cactions were ideassignable (cc	eported that on, had not as schedule ine case pe ary of invest defect is no entified as a	the reason to tested for ed the second r medical igations was r t representativall reviewed confirmed).
Lab Data:		Unknowr	l			La	b Data							
Lab Narrative:														
Test Name		Normal V	alue	Test Dat	te	Test Result			Lab C	comments				
					Susn	ect Product(	s) Therany	Informatio	n					
Suspect Product(s	)	Unit Dose	Total Daily	/ Dose	Regimen Do		of Admin			Therapy Duration	Anatomica Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2						NO DA		)9-AUG-2( )9-AUG-2(			ARM LEFT	1	FF2154	
					1	ı					<del>'</del>	FDA-CBER-20	<del>22-5812-02</del>	35516





					5	Suspect Produ	uct(s) Inform	ation						
Suspect Prod	uct(s)	Indica	ation(s)		Form of Adn	nin First 1	otal Daily D	ose Acti	on Taken	Dechal	lenge	Rechall	enge	Interacting Drug
3NT162B2		COVI	D-19 immun	isation	SOLUTION F INJECTION	OR		NOT	T APPLICABLE	N/A		N/A		NO DATA
					Pro	oduct(s) and E	vent(s) Info	rmation						
Suspect Prod	uct(s)	Event(s	)		CDS	Latency	Group	Recha	llenge	Causali	ty per Repo	rter	Causality	per Company
BNT162B2		Respirat	ory failure		N	Post Ther	ару	N/A		N/A			N/A	
BNT162B2		Circulato	ory collapse		N	Post Ther	ару	N/A		N/A			N/A	
						Patient Mo	edical Histor	у						
Patient/Parent	Indicator	Coded Condition	an .	Start Date	Stop Date	Ongoin	n Note	•						
ationiti areni	indicator	Coded Condition	<u> </u>	Jotait Bate	Otop Bate	_	Death/Autop							
Other Death In	formation:					Ouuse of L		,						
Гуре		Patient/Parent I	ndicator	Coded Conditi	on				Notes					
DEATH		PATIENT	-	Circulatory colla	apse									
DEATH		PATIENT	I	Respiratory fail	ure									
ConMed: U	Inknown					Concomi	tant Produc	:(s)						
Concomitant I	Product(s)		Conmed Tr	adename As I	Reported	Therapy Dat	e(s)				Route	of Admin		
						-								
						Suspect or C	onmed Dev	ces						
Suspect Device														
Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available Evaluation			Single Use	Evaluation Type	n Evaluation	on Code
NO DATA							NO DATA	NO DATA	A NO DA	TA				
						Pena	rt History							
Source		HP/Medically Confirmed	Case Rep	ort Type	Reporter	Occupation	Protocol/S	tudy No.	Center ID	& Other ID	Patient II	D Ini	tial Safety ceipt Date	EUDRACT No
Spontaneous		N	SPONTAI	NEOUS	NA								-AUG-2021	



Page 23 of 36

As of Date: 01-OCT-2021

Section Page: 3

7.AER Number (b) (6) Case Seriousness: SERIOUS Seriousness Criteria: Death, Medically Significant

		References	
Reference Type	Reference ID	Reference Notes	
COVAES REFERENCE NO.	(b) (6)		
E2B COMPANY NUMBER	(b) (6)		
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)	
PRODUCT COMPLAINT NO.	(b) (6)	(b) (6)	
,		Parent Medical History	
Patient/Parent Indicator Coded	Condition Start Date	Stop Date Ongoing Notes	





8.AER Number	(	(b) (6)		Ca	ase Seriou	ısness: SE	ERIOUS	Serious	ness Cri	<b>iteria:</b> D	eath						
							Pati	ient Demograp	hic								
Sex	Age			Height	(cm)		Weight	t (kg)	Race			Country V	/here Event	Occured			
MALE	15 YEAF	RS							NO D	ATA - NO	DATA	SPAIN					
						Е	vent Inf	ormation and I	Narrativ	9							
Verbatim Term	L	owest Le	evel Term		Preferre	d Term		Onset Da	te	Event Seriousn		linical Out		Procedure Sausality P Company		Proced Per Rep	ure Causality porter
Sudden death unexpla	ined S	Sudden de	eath unexp	ained	Sudden	death		09-AUG-2	021	SERIOUS	S F	ATAL	N	IO DATA	1	NO DAT	Ā
Cardiorespiratory arres	st C	Cardio-res	piratory arı	est	Cardio-re	espiratory arre	est	09-AUG-2	021	SERIOUS	S F	ATAL	N	IO DATA	١	NO DAT	Ā
This is a spontaneous dose of bnt162b2 (COI bnistory. The patient corpulse. Some stiffness of 00:00. It was unknown No follow-up attempts	MIRNATY ncomitant of limbs. T if autops	Y, Solutior t medicati There is n sy has bee	n for injections were no prior Car lo prior Car len done. Th	on, Lot nun ot reported diorespirat ne outcome	nber: unkno l. On 09Au ory arrest. of the eve	own), via an u g2021 at 09:0 Time of evolu ents was fatal.	nspecifie	ed route on 02À	ug2021 : v family	as a single found the i	do patient with	(b) (6) out a pulse otocol is ac	tion. T Upon arriva	he patient l	has no pi nergency	rior hist	ived unknown ory medical ne has no 09Aug2021
Lab Data:			Unknowi	า				Lab Data									
Lab Narrative:																	
Test Name			Normal \	/alue	Test Date	•	Test Re	esult		Lab (	Comments						
<u> </u>																	
ļ.						Susp	ect Prod	duct(s) Therapy	Inform	ation							
Suspect Product(s)		Ur	nit Dose	Total Daily	Dose	Regimen Do	se Ro	oute of Admin	Therap	y Date(s)	Therapy	Duration	Anatomical Location	Vaccinat Dose No		No.	Batch No.
BNT162B2							NC	ATAD C	02-AUG 02-AUG	G-2021 - G-2021	1 DAY(S)		NO DATA	1	Unk	nown	
						S	Suspect	Product(s) Info	rmation	1							
Suspect Product(s)		In	dication(s	)		Form of Adn	nin F	First Total Daily	Dose	Action Ta	aken	Dechalle	nge	Rechaller	nge	Inter	acting Drug
BNT162B2 COVID-19 immunisation SOLUTION FOR INJECTION							OR			NOT APP	PLICABLE	N/A		N/A		NO I	DATA
						Pro	duct(s)	and Event(s) li	nformati	on							
Suspect Product(s) Event(s) CDS Latency Group Rechallenge Causality per Reporter Causality per Compan										Company							
BNT162B2		Sudo	den death			N	Post	t Therapy	N	/A		N/A			N/A		
BNT162B2		Card	lio-respirato	ory arrest		N	Post	t Therapy	N	/A		N/A			N/A		





8.AER Number		(b) (6)		Case Serie	ousness: SE	RIOUS	Seriousnes	s Criteria:	Death					
						Patient Mo	edical Histor	у						
Patient/Parent I	ndicator	Coded Condit	ion	Start Date	Stop Date	Ongoin	g Notes	<b>S</b>						
Other Death Info						Cause of D	Death/Autops	sy						
Other Death Info		Patient/Parent	Indicator	Coded Condit	ion				Notes					
DEATH		PATIENT		Cardio-respirat					11000					
'9	known				,	Concomi	tant Product	(s)						
Concomitant P	roduct(s)		Conmed T	radename As	Reported	Therapy Dat	e(s)			Rou	te of Admin	-		
<del>4</del>						-								
1	Suspect or Conmed Devices													
Suspect Devices														
Tipevice Type O II	Device Type Device Indicator Model No. Serial No. NDC No. Date of Manufacture Catalog No. Device Operator Device Evaluated by Manufacture Nation Device Evaluation Manufacture Nation Nation National Nation National Nation National Nationa													
NO DATA							NO DATA	NO DATA	NO DATA					
<u></u>						Repo	rt History							
orsource ⊆		HP/Medicall Confirmed	y Case Re	port Type	Reporter	Occupation	Protocol/S	tudy No.	enter ID & Other II	D Patient		al Safety eipt Date	EUDRACT No.	
Spontaneous		Y	SPONTA	NEOUS	PHYSICIA	۱N					01-8	EP-2021		
					,	Refe	erences							
Reference Type	)	Re	eference ID		I	Reference No	tes							
E2B AUTHORIT	Y NUMBER		(b) (6)		(	b) (6)								
E2B REPORT D	UPLICATE		(b) (6)		(	b) (6)								
5)		0 - 1 - 1 0 111		lott Dt	lot D (		edical Histor							
Patient/Parent I	ndicator	Coded Condit	ion	Start Date	Stop Date	Ongoin	g Notes							





9.AER Number		(b) (6)		C	ase Serio	usness: S	ERIOUS	S Seriou	sness	Criteria:	Death						
							Pa	tient Demogra	phic								
Sex	Age			Height	(cm)		Weigh	nt (kg)	Ra	ice		Country \	Where Event	Occured			
MALE	14 YEAI	RS							NC	DATA - N	IO DATA	SPAIN					
							Event In	formation and	Narra	tive							
Verbatim Term	I	Lowest Le	evel Term		Preferr	ed Term		Onset D	ate	Event Seriou		Clinical Ou	c	rocedure ausality P ompany		Proced Per Re	ure Causality porter
pulmonary edema	I	Pulmonary	edema		Pulmon	ary oedema		03-SEP-	2021	SERIO	US	FATAL	N	IO DATA	١	O DA	ГА
This is a spontaneous Pfizer company docto A 14-year-old male pa administration as sing died on 03Sep2021. T	r. itient rece le dose fo	eived bnt16 or COVID-	62b2 (CON 19 immuni:	//IRNATY), zation. Med	1st dose dical histor	on 06Jul2021 v none. Cond	(Lot Nu	mber: EX0893)	and 2r	nd dose on	27Jul2021 (	Lot Number	: EW2246. bo	oth via an u	nspecifie	d route	e of
Lab Data:			Unknow	n				Lab Data									
Lab Narrative:																	
Test Name			Normal \	<b>Value</b>	Test Dat	e	Test R	Result		La	b Commen	ts					
<b>*</b>																	
						Susi	ect Pro	duct(s) Thera	oy Info	rmation							
Suspect Product(s)		Ur	nit Dose	Total Dail	y Dose	Regimen Do	ose R	Route of Admir	Ther	apy Date(s	s) Therapy	Duration	Anatomical Location	Vaccinat Dose No.		No.	Batch No.
BNT162B2							N	IO DATA		JL-2021 - JL-2021	1 DAY(S	5)	NO DATA	1	EX0	893	
BNT162B2							N	IO DATA		JL-2021 - JL-2021	1 DAY(S	5)	NO DATA	2	EW2	2246	
							Suspec	t Product(s) In	format	ion							
Suspect Product(s)		In	dication(s	)		Form of Ad	min	First Total Da	ily Dos	e Action	Taken	Dechall	enge	Rechaller	nge	Inte	racting Drug
BNT162B2		CO	OVID-19 in	nmunisatio	n	SOLUTION INJECTION	FOR			NOT A	PPLICABLE	N/A		N/A		NO	DATA
						Pr	oduct(s	) and Event(s)	Inform	ation							
Suspect Product(s)		Ever	nt(s)			CDS	La	tency Group		Rechalle	nge		y per Report			y per (	Company
BNT162B2		Pulm	onary oed	ema		N	Po	st Therapy		N/A		N/A			N/A		
							Pat	ient Medical H	istory								
Patient/Parent Indica	tor Co	ded Cond	lition	Sta	rt Date	Stop Date	0	ngoing	Notes								
														DA CRED	2022 58	12 023	5521





9.AER Numbe	r	(b) (6)		Case Serio	ousness: SE	ERIOUS	Seriousnes	s Criteria:	Death					
						Cause of D	Death/Autops	sy						
Other Death In	formation:													
Туре		Patient/Paren	t Indicator	Coded Conditi	on				Notes					
DEATH		PATIENT		Pulmonary oed	ema									
	Jnknown		_			T	tant Product	(s)			1			
Concomitant	Product(s)		Conmed T	radename As I	Reported	Therapy Date	e(s)				Route	of Admin		
<b>₹</b>			1			-								
4						Suspect or C	onmed Devi	ces						
Suspect Devi														
Device Type	Indicator Manufacture Operator Available for Evaluated by Type													
NO DATA NO DATA NO DATA														
Щ						Repo	rt History							
Source		HP/Medical Confirmed		oort Type		Occupation	Protocol/S	tudy No.	enter ID & Other II	D Pat	tient IE		al Safety eipt Date	EUDRACT No.
Spontaneous		N	SPONTA	NEOUS	NA							07-S	EP-2021	
i <del>l</del>						Refe	erences							
Reference Ty	pe	R	eference ID			Reference No	tes							
Reference Tyl		(b	) (6)		(	(b) (6)								
E2B COMPAN	IY NUMBER		(b)	(6)										
PRODUCT CC	MPLAINT N	O. (k	o) (6)			(b) (6)								
RPRODUCT CC	MPLAINT N	0.	(b) (6)			(b) (6)								
70							edical Histor							
Patient/Paren	t Indicator	Coded Condit	ion	Start Date	Stop Date	Ongoing	g Notes	3						





10.AER Number		(b) (6)		Ca	ise Serio	usness: SE	ERIOU	IS <b>Serio</b>	usness	Criteri	ia: D	eath,Medio	cally Signific	cant				
							P	atient Demog	raphic									
Sex	Age			Height	(cm)		Weig	ıht (kg)	Ra	асе			Country V	here Event	Occured			
MALE	15 YEA	ARS							NO	D DAT	A - NO	DATA	GREECE					
				·		E	vent I	nformation ar	nd Narra	tive								
Verbatim Term		Lowest Lo	evel Term		Preferre	ed Term		Onset		Ev	ent eriousn		Clinical Out	c	rocedure ausality Pe ompany		ocedure er Repor	Causality ter
Sudden death		Sudden de	eath		Sudden	death		13-SEF	P-2021	SE	RIOUS	S F	ATAL	N	O DATA	N	DATA	
This is a spontaneous	report fr	rom a conta	actable ph	ysician dowr	nloaded fr	om the Europe	ean Me	edicines Agenc	y (EMA)	Eudra	Vigiland	ce-WEB, re	gulatory au	thority numb	er (k	o) (6)		
A 15-year-old male pat concomitant medicatio No follow-up attempts						ntramuscular o lden death on	on 10S 13Sep	ep2021 (Batch 2021. The pati	/Lot Nun ient died	nber: F on 139	G4442 Sep202	) as single 1. An autop	dose for co osy was pe	vid-19 immur rformed and	nisation. The results were	e patient not prov	medical ł ided.	nistory and
Lab Data:			Unknow	/n				Lab Data										
Lab Narrative:			•															
Test Name			Normal	Value	Test Dat	e	Test I	Result			Lab (	Comments	<b>S</b>					
₫																		
<u> </u>						Susp	ect Pr	oduct(s) Thera	apy Info	rmatio	n							
Suspect Product(s)		Uı	nit Dose	Total Daily	Dose	Regimen Do	se I	Route of Adm	in Ther	apy D	ate(s)	Therapy	Duration	Anatomical Location	Vaccination Dose No.	on Lot N	o. Ba	atch No.
BNT162B2								INTRAMUSCU AR		EP-20 EP-20		1 DAY(S)		NO DATA	1	FG44	42	
						S	Suspe	ct Product(s) I	Informat	ion								
Suspect Product(s)		In	dication(s	s)		Form of Adm	nin	First Total D	aily Dos	e Ad	ction Ta	aken	Dechalle	nge	Rechallen	ge	Interac	ting Drug
BNT162B2		C	OVID-19 ir	mmunisation	1	SOLUTION F INJECTION	OR			NO	OT APP	PLICABLE	N/A		N/A		NO DA	ГА
						Pro	duct(s	s) and Event(s	s) Inform	nation								
Suspect Product(s)		Evei	nt(s)			CDS	La	atency Group		Rech	allenge	е	Causality	per Report	er C	Causality	per Cor	npany
BNT162B2		Sudo	den death			N	Po	ost Therapy		N/A			N/A		N	I/A		
							Pa	tient Medical	History									
Patient/Parent Indica	tor C	oded Cond	dition	Sta	rt Date	Stop Date		Ongoing	Notes									
Other Dead I C							Cai	use of Death/A	Autopsy									
Other Death Information	on:													F	DA-CRER-2	0022-581	2-023552	23





10.AER Num	ber	(b) (6)		Case Serie	ousness: SE	ERIOUS	Seriousne	ss Criteria:	Death,Medically Sig	nificant				
Туре		Patient/Parent	Indicator C	oded Condit	ion				Notes					
DEATH		PATIENT	S	udden death										
ConMed:	Unknown					Concomi	tant Produc	t(s)						
Concomitan	t Product(s)		Conmed Tra	dename As	Reported	Therapy Date	e(s)				Route	of Admin		
						-								
						Suspect or C	onmed Dev	ices						
Suspect Dev	/ices													
NO DATA		Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Singl	e Use	Evaluation Type	Evaluation	on Code
NO DATA							NO DATA	NO DATA	NO DATA					
						Repo	rt History							
Source		HP/Medicall Confirmed	y Case Repo	ort Type	Reporter	Occupation	Protocol/	Study No.	Center ID & Other I	D Pa	tient IC		al Safety eipt Date	EUDRACT No.
Spontaneous	3	Y	SPONTAN	EOUS	PHYSICIA	AN						20-S	EP-2021	
)						Refe	erences							
Reference T	уре	Re	eference ID		I	Reference No	tes		•					
E2B AUTHO	RITY NUMBE	R	(b) (6)			(b) (6)								
E2B REPOR	T DUPLICATE		(b) (6)			(b) (6)								
PRODUCT C	OMPLAINT N	10. (b	) (6)			(b) (6)								
	OMPLAINT N		(b) (6)		(	(b) (6)								
<b>1</b>						Parent Me	dical Histo	У						
Patient/Pare	nt Indicator	Coded Condit	ion	Start Date	Stop Date	Ongoing	Note	s						
) )														





Suspect Product(s)

BNT162B2

Unit Dose

Total Daily Dose

Regimen Dose

Section Page: 1

11.AER Number	(	(b) (6)	Case	e Seriousness: SE	ERIOUS	Seriousne	ss Criteri	ia: Death,Hos	spitalization Required					
					Patient	Demographi								
Sex	Age		Height (c	m)	Weight (kg)	)	Race		Country Where Eve	nt Occured				
MALE	12 YEAR	RS	145.0		39.0		NO DAT	A - NO DATA	GERMANY					
				E	vent Informa	ation and Na	rrative							
Verbatim Term Lowest Level Term Preferred Term Onset Date Event Seriousness Clinical Outcome Causality Per Causality Per Company Unknown cause of death Unknown cause of death Death Death Death Death Death Clinical Outcome Causality Per Causality Per Company Procedure Causality Per Company Procedure Causality Per Company Procedure Causality Per Company Procedure Causality Per Company  Death Dea														
Unknown cause of dea	ath U	Jnknown cause of deat	h [	Death		20-AUG-202	1 SE	RIOUS	FATAL	NO DATA	NO DATA			
Pyrexia	Р	Pyrexia	F	Pyrexia		20-AUG-202	1 SE	ERIOUS	NOT RECOVERED/NOT RESOLVED	NO DATA	NO DATA			
Unwell	U	Jnwell	N	Malaise		20-AUG-202	1 SE	ERIOUS	NOT RECOVERED/NOT RESOLVED	NO DATA	NO DATA			
Dyspnoea	D	yspnoea	1	Dyspnoea		20-AUG-202	1 SE	ERIOUS	NOT RECOVERED/NOT RESOLVED	NO DATA	NO DATA			
This is a spontaneous Report Unique Identifie	report fro	m a consumer or other (b) (6)	non hcp d	ownloaded from the E	uropean Med	licines Agenc	y (EMA) E	EudraVigilance-	(b) (6)	and Send	der's (Case) Safety			
thospitalization. The pa	atient's me d with Co ath. The p you or th tors or pre for events	edical history and concumirnaty (mRNA TOZIN attent's outcome was: ne person concerned keyoious illnesses: none / s /PEI / : D. Unclassifial	urrent cond IAMERAN) not recover nown of any malaise, fo ble	litions included: no rele , unknown dosage. Co red/not resolved for Dy y allergies? If yes, whi ever, palpitations and	evant medica oncomitant mo yspnoea, fata ch? no shortness of	I history repo edications we I for Unknowi	ted. The re: no co n cause of	patient's weight ncomitant medic f death.	was 39 kg, and height v	was 145 cm.	This report is serious - experienced Dyspnoea,			
Lab Data:		Unknown			La	ab Data								
Lab Narrative:		'												
Test Name		Normal Val	ue To	est Date	Test Result			Lab Commer	its					
<u>,                                    </u>		<u> </u>		Susp	ect Product(	s) Therapy II	nformatio	on .						

Unknown

Batch No.

Anatomical Vaccination Lot No. Location Dose No.

NO DATA

NO DATA

Route of Admin | Therapy Date(s) | Therapy Duration

1 DAY(S)

19-AUG-2021 -19-AUG-2021





					S	uspect Prod	uct(s) Inforr	nation							
Suspect Produ	ıct(s)	Indic	ation(s)		Form of Adm	in First	Total Daily D	Oose A	ction Tal	cen D	echalle	enge	Rechall	enge	Interacting Dru
BNT162B2		COV	D-19 immur	isation	SOLUTION F INJECTION	OR		N	OT APPL	ICABLE N	I/A		N/A		NO DATA
		·			Pro	duct(s) and	Event(s) Info	ormation	ı						
uspect Produ	ıct(s)	Event(s	)		CDS	Latency	Group		hallenge	С	ausalit	y per Repo	rter	Causality	per Company
NT162B2		Death			Х	Post The	rapy	N/A		N	I/A			N/A	
NT162B2		Pyrexia			Х	Post The	гару	N/A		N	I/A			N/A	
NT162B2		Malaise			X	Post The	rapy	N/A		N	I/A			N/A	
					X			N/A						N/A	
BNT162B2		Dyspno	ea		X	Post The	rapy	N/A		IN.	I/A			N/A	
						Patient M	edical Histo	ry							
				1			1								
atient/Parent	Indicator	Coded Condition	on	Start Date	Stop Date	Ongoin	_								
Other Death Inf	ormation.					Cause of	Death/Autop	sy							
ype		Patient/Parent	ndicator	Coded Condition	on					Notes					
EATH		PATIENT		Cardiac arrest											
onMed: U	nknown					Concom	itant Produc	ct(s)							
oncomitant F	Product(s)		Conmed T	radename As R	eported	Therapy Da	te(s)					Route	of Admin		
						-									
						Suspect or (	Conmed Dev	/ices							
uspect Devic	es														
Suspect Devic Device Type	Device Indicator	Model No.	Serial No.		Date of Manufacture	Catalog No.	Device Operator	Device Availa Evalua	ble for	Device Evaluated Manufactu	by	Single Use	Evaluation Type	n Evaluati	on Code
IO DATA							NO DATA	NO DA	ATA	NO DATA					
Source						Repo	rt History								
ource		HP/Medically Confirmed	Case Rep	oort Type	Reporter	Occupation	Protocol/	Study No	o. Cei	nter ID & Ot	her ID	Patient II	D Init	ial Safety ceipt Date	EUDRACT No
		1	<b>I</b>												



Page 32 of 36 As of Date: 01-OCT-2021



11.AER Number	(b) (6)	Case Seriousness:	SERIOUS	Seriousness Criteria:	Death, Hospitalization Required
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		Referen	ces
Reference Type	Reference ID	Reference Notes	
E2B AUTHORITY NUMBER	(b) (6)	(b) (6)	
E2B REPORT DUPLICATE	(b) (6)	(b) (6)	
E2B REPORT DUPLICATE	(b) (6)	(b) (6)	
E2B REPORT DUPLICATE	(b) (6)	(b) (6)	
5		Parent Medic	al History
Patient/Parent Indicator   Coded C	ondition Start	Date Stop Date Ongoing	Notes



Page 33 of 36

As of Date: 01-OCT-2021

12.AER Number	(b) (6	<b>i</b> )	Ca	ase Serio	usness: SE	ERIOUS	Serious	ness Crite	ria: D	)eath					
						Patien	t Demograp	hic							
Sex	Age		Height	(cm)		Weight (k	g)	Race			Country V	/here Event	Occured		
FEMALE	12 YEARS							NO DA	TA - NO	DATA	ITALY				
					E	vent Inforn	nation and I	Narrative							
Verbatim Term	Lowes	t Level Term		Preferre			Onset Da	te E	vent Seriousn		Clinical Ou	ļc	Procedure Sausality Per Company	Proced Per Re	ure Causality porter
Sudden death	Sudde	n death		Sudden	death		SEP-20	21 S	ERIOUS	3	FATAL	N	IO DATA	NO DA	TA
This is a spontaneous A 12-years-old female SINGLE for covid-19 in unspecified date in Se Additional information Does Pfizer have perm Does Pfizer have perm Reason why batch/lot Did the patient receive Reported Event: Sudd Prior to vaccination, wisince the vaccination, Follow-up (29Sep2021 ER # (b) (6)	patient receive nmunisation. Tp2021. It was provided includission to contanission to contanission to contanission to contanis Unknown: No any other vaccen death as the patient dhas the patient dhas the patient or additional information of the parents about	d bnt162b2 (BI The patient mere not reported if ed: ct the reporter ct your/the patient available/pro sines within 4 w ilagnosed with been tested for formation provid She said she if 3 weeks ago, t	NT162B2), dical history an autops about this ent's healt vided to reveeks prior COVID-19 or COVID-1 ded by the mad no furth he day after an autops and the covident of the cov	via an unsy was not y was not y was perfected by was perfected by was perfected by was porter at the CO of	specified route reported. The formed.  Ses vider about this he time of reported. The time of reported in the time of reported	e of administ ne patient's s report?:No ort completio Inknown umer include she heard i 162B2 (unkn	concomitant on ed the followi	medication	porter wa	as contac	ted as per th	ent experiende e immediate	follow-up activ	ath (sudden ity of A	death) on
Lab Data:		Unknowr	)				Lab Data								
Lab Narrative:		'													
Test Name		Normal V	'alue	Test Date	e	Test Resu	lt		Lab (	Commen	ts				
					Susp	ect Produc	t(s) Therapy	Informati	ion						
Suspect Product(s)		Unit Dose	Total Daily	/ Dose	Regimen Do	se Route	e of Admin	Therapy	Date(s)	Therapy	Duration	Anatomica Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2						NO D	ATA	-				NO DATA			





12.AER Numbe	r	(b) (6)		Case Serio	ousness: SE	ERIOUS	Seriousnes	Criteria:	Death					
					S	Suspect Prod	uct(s) Informa	ition						
Suspect Produc	ct(s)	Indi	cation(s)		Form of Adn	nin First	Total Daily Do	se Action	Taken	Dechalle	enge	Rechalle	nge	Interacting Drug
BNT162B2		CO/	/ID-19 immunis	ation	SOLUTION F INJECTION	OR		NOT A	PPLICABLE	N/A		N/A		NO DATA
					Pro	duct(s) and I	Event(s) Infor	mation						
Suspect Produ	ct(s)	Event(	s)		CDS	Latency	Group	Rechaller	nge	Causalit	ty per Repo	rter	Causality	per Company
BNT162B2		Sudde	n death		X	Unknown		N/A		N/A			N/A	
1						Patient M	edical History	1						
Patient/Parent	Indicator	Coded Condit	ion	Start Date	Stop Date	Ongoin	g Notes							
1						Cause of I	Death/Autops	у						
Other Death Info														
Туре		Patient/Parent		oded Conditi	ion				Notes					
DEATH		PATIENT	Su	ıdden death										
	known		I		<b>.</b>		tant Product	s)			- I- 1			
Concomitant P	roduct(s)		Conmed Trac	dename As I	Reported	Therapy Dat	e(s)				Route	of Admin		
<u>{</u>			<u> </u>			-								
Supposed Bassics						Suspect or 0	Conmed Devi	ces						
Suspect Device	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation		ed by	Single Use	Evaluation Type	Evaluation	on Code
NO DATA							NO DATA	NO DATA	NO DAT	Α				
<del>}</del>						Repo	rt History							
Source		HP/Medicall Confirmed	y Case Repo	rt Type	Reporter	Occupation	Protocol/S	udy No.	Center ID &	Other ID	Patient ID		al Safety eipt Date	EUDRACT No.
Spontaneous		N	SPONTANE	EOUS	NA							28-8	SEP-2021	
						Ref	erences							
Reference Type	9	Re	ference ID		I	Reference No	tes							
COVAES REFE	RENCE NO		(	b) (6)										
							edical History							
Patient/Parent	Indicator	Coded Condit	ion	Start Date	Stop Date	Ongoin	g Notes							





13.AER Number

(b) (6)

Case Seriousness:

SERIOUS

Seriousness Criteria: Death

Section Page: 1

						P	atient Demograp	hic								
Sex	Age		Height	(cm)		Weig	ht (kg)	Rac	е		Country W	/here Event	Occured			
MALE	13 YEAF	RS						NO	DATA - NO	DATA	GERMANY	′				
					E	vent I	nformation and	Narrati	ve							
Verbatim Term	I	Lowest Level Term		Preferre	ed Term		Onset Da	ite	Event Seriousn		Clinical Out	l c	Procedure Causality F Company		Procedu Per Rep	re Causality orter
death	1	Death		Death					SERIOUS	6 F	ATAL	N	IO DATA	1	NO DAT	A
This is a spontaneous license party for BNT1 date for COVID-19 im for a PMR project in G Follow-up (22Jul2021) No follow-up attempts	62B2 (Comunization ermany.	OMIRNATY). A 13-yin. Medical history are Cause of death was ormation reported in	ear-old male id concomi not provide cludes: eve	e patient r tant medic d. It was u	eceived the se ations were no unknown if an	econd of ot repo autops	dose of BNT162B orted. The patient by was performed	2 (COM had die . The ou	MIRNATY) vied on an uns utcome of ev	a an unspe pecified da	cified route te. Reporte	of administr	ation at sir	igle dose	on an u	nspecified
							Case Comment	s								
Based on the information currently available, a possible contributory role of the suspect vaccine BNT162B2 on causing the event death cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this period as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.													efit/risk profile of this			
Lab Data:		Unknow	า				Lab Data									
Lab Narrative:																
Test Name		Normal '	/alue	Test Dat	е	Test I	Result		Lab	Comment	3					
<b>*</b>					Susp	ect Pro	oduct(s) Therap	y Inforr	mation							
Suspect Product(s)		Unit Dose	Total Daily	/ Dose	Regimen Do	se I	Route of Admin	Thera	py Date(s)	Therapy	Duration	Anatomica Location	Vaccina Dose No		No.	Batch No.
BNT162B2						1	NO DATA	-				NO DATA	2			
		·			5	Suspec	ct Product(s) Infe	ormatio	on	•						
Suspect Product(s)		Indication(s	)		Form of Adn	nin	First Total Dail	y Dose	Action T	aken	Dechalle	nge	Rechalle	nge	Inter	acting Drug
BNT162B2		COVID-19 ir	nmunisation	1	SOLUTION F INJECTION	OR			NOT APF	PLICABLE	N/A		N/A		NO E	)ATA
		•			Pro	duct(s	s) and Event(s) I	nforma	ation							
Suspect Product(s)		Event(s)			CDS	Lá	atency Group		Rechalleng	e	Causality	per Report	er	Causali	ty per C	ompany
BNT162B2 Death N Unknown N/A N/A N/A N/A																

FDA-CBER-2022-5812-0235530





13.AER Number	r	(b) (6)		Case Seri	ousness: SE	ERIOUS	Seriousnes	s Criteria:	Death					
						Patient Mo	edical Histor	у						
Patient/Parent I	Indicator	Coded Cond	tion	Start Date	Stop Date	Ongoin	g Notes	3						
				1			Death/Autops							
Other Death Info	ormation:													
Туре		Patient/Pare	t Indicator	Coded Condit	ion				Notes					
DEATH		PATIENT		Death										
<del> </del>	known		T				tant Product	:(s)						
Concomitant Pi	roduct(s)		Conmed Ti	adename As	Reported	Therapy Dat	e(s)				Route	of Admin		
<u> </u>						-								
						Suspect or C	conmed Devi	ces						
Suspect Device Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for	Device Fvaluated by Manufacturer	Single		Evaluation Type	Evaluatio	n Code
								Evaluation						
NO DATA							NO DATA	NO DATA	NO DATA					
						Repo	rt History			·				
Source		HP/Medica Confirmed	lly Case Rep	ort Type	Reporter	Occupation	Protocol/S	tudy No.	Center ID & Other	ID Pat	ient ID		al Safety eipt Date	EUDRACT No.
Spontaneous		Y	SPONTAI	NEOUS	OTHER H PROFESS	EALTH SIONAL						07-J	UL-2021	
		Y	SPONTAI	NEOUS	PHYSICIA	AN								
						Refe	erences							'
Reference Type	)	F	eference ID		I	Reference No	tes		-					
E2B REPORT D	UPLICATE		o) (6)			(b) (6)								
LICENSE PART	NER NO.	(1	) (6)			(b) (6)								
E2B COMPANY	NUMBER		(b) (	6)		D( 11	-1!111!-1							
Patient/Parent I	Indicator I	Coded Cond	tion	Start Date	Ston Data		edical Histor							
Patient/Parent i	indicator	Coded Cond	uon	Start Date	Stop Date	Ongoin	Notes							